QRS-104 Special Processes

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QRS-104
Special Processes

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CHANGES LOG

Issue	Approval Date	Main changes	Interested Paragraphs
00	April 2015	First Issue – Supersedes IQ S004 rev. C	All
01	June 2018	Document significantly rewritten and reformatted	All
02	June 2019	Editorial changes and clarifications Reference to Annex 1 removed	2; 5.2.1; 8 10; Appendix 2

APPLICABLE DOCUMENTS

This document *shall* be applied together with the main document (QRS-01 Quality Requirements for Suppliers) and with the other applicable modules

CONTENTS

1 Purpose

Purpose of this procedure is to indicate how to proceed if Special Processes are defined on parts and how to manage qualification, qualification renewal and requalification. Special Processes *shall* be performed by qualified personnel, utilizing approved equipment, methods and materials.

Qualification is synonymous of *Validation*, to the extent of this procedure

The LH Special Processes are defined in Appendix 2. See QRS-01 for definitions of LH Supplier categories.

2 Applicability

This procedure, except paragraph 8, applies to:

- *Subcontractors* and *Offload* suppliers performing Special Processes per LH Process Specifications (AWPS, STA, WHPS etc.), National and International Specifications (MIL, AMS, ASTM etc.), Licensee/Partner/Customer Specifications.
- *Manufacturer* Suppliers performing Special Processes per LH Process Specification (AWPS, STA, WHPS etc.)

Paragraph 8 of this procedure applies to:

- *Manufacturer* Suppliers performing Special Processes against International or Proprietary Specifications

3 Effective date

Issue date

4 Acronyms, definitions and abbreviations

4.1 Acronyms and abbreviations

DQP	Declaration for Qualification of the Process
QC	Quality Control
RFVA	Request For Variation Approval
SQA	Supplier Quality Assurance

4.2 Definitions

Special Process: Special Processes are those individual processes whose results on the product cannot be completely verified by measurements or objective checks, and where discrepancies can affect in service performance of the parts. Special Processes require approval and review, and *shall* be qualified prior to use. The definition also

includes Processes performed with portable equipment/devices or only by personnel where applicable.

5 Requirements

5.1 Introduction

When Special Processes are required by drawings or other Engineering requirements for manufacturing operations or inspection, the Supplier *shall*:

- identify the Special Processes and the applicable process specifications on the manufacturing documentation;
- check all the aspects relevant to the Special Process (such as material, equipment, personnel, procedures and software) so that the produced results are repeatable;
- define the significant operations and process parameters to be controlled during production;
- use only approved sources for Special Processes

Special Processes *shall* be qualified before being used.

Any modification to operations and parameters requires their requalification and justification.

The Supplier *shall* include in his control records the objective evidence of the use of qualified Special Processes.

5.2 Special Process Initial Qualification

It is Supplier responsibility to require the initial Qualification to LH Procurement, specifying the required scope of approval. LH Procurement *shall* inform SQA, who will identify and involve the competent LH Laboratory that will conduct the Special Process assessment, in direct contact with the Supplier for qualification activities.

Prior to apply for qualification, the supplier *shall*:

- Achieve a LH SQA System approval suitable for Special Processes
- Achieve a Nadcap certification in case the Special Process is identified by Nadcap in Appendix 2, or submit a Nadcap accreditation plan acceptable to LH
- Identify in detail the required scope of approval, in terms of special processes and Process Specifications
- Perform a gap analysis against the applicable process specifications/requirements, and make any implementations needed to achieve and assure compliance.

The Supplier *shall* prepare and submit to LH a qualification report, according with Appendix 1, as part of the qualification activities.

The LH verifications activities can include visits/audits at the supplier site, documental checks, testing and any other verifications deemed necessary by the LH Laboratory for the evaluation of the process effectiveness.

The Initial Qualification Report, as well as any Requalification and Renewal Reports (see Appendix 1), *will* be sent directly by the Supplier to the assigned LH Laboratory.

The report will contain a completed checklist which demonstrates compliance with all paragraphs of the LH technical specifications.

Any deviations from the applicable Process Specifications can only be accepted if approved by LH Engineering through RFVA (see paragraph 7)

Alleviations for Special Processes Nadcap approved are described in paragraph 5.6 for first Qualification, Renewal and Requalification.

5.2.1 Approval document: DQP

The document sent to the Supplier by LH to grant Special Process approval is the DQP (see Appendix 3). The DQP *shall* be displayed on the equipment or as close as possible within the facility in relation to layout and nature of the process.

The Approval (DQP) has three years validity unless a lower frequency is defined by LH or by contract.

Not approved Special Processes *shall* not be used for LH products.

5.2.2 Initial Qualification Report

It is a fundamental document for the purposes of obtaining the Qualification.

The tests and the qualification report *shall* be in accordance with the requirements in Appendix 1.

Any Technique Sheets for NDT *shall* be managed and approved according to the requirements of AWPS009X.

Any Technique Sheets for other Special Processes *shall* be previously approved by LH where requested by the applicable Process Specifications.

5.3 Process Controls Testing (maintenance checks)

Every system is subject to a periodical checks program for the maintenance of the qualification in compliance with applicable process specifications and to the DQP directives.

Process control tests and checks per applicable specifications/requirements *shall* be performed under Supplier responsibility.

The process control tests/checks *shall* be recorded.

In case of deterioration of the system performances from the process control testing, preventive actions *shall* be put in place before test failures.

In case of test failures, the processor is responsible to ensure appropriate investigations and corrective actions, informing QC of the LH plant if a product impact is suspected.

The process control tests listed in the DQP should reflect at least the minimum process control tests and checks per applicable process specifications. This list on the DQP may be a list of high level callouts to applicable specifications /procedures. In case of conflict with the DQP list, the applicable Process Specifications *shall* prevail and any deviations in the process control testing requirements *shall* be authorized by LH Engineering through deviation (RFVA) according with paragraph 7.

A detail process control system *shall* be implemented by the Supplier, who is directly responsible for process control testing compliance to Specifications / Engineering requirements.

5.4 Qualification Renewal (at DQP expiration)

The Supplier who wants to apply for validation renewal *shall* send to the applicable LH Laboratory manager, at least 3 months before the DQP expiry date, the validation report with the contents of Appendix 1.
The validation renewal requires the re-issue of the DQP and *shall* be performed as the initial validation unless differently specified by the applicable specifications.

5.5 Requalification

The requalification of a special process *shall* be performed when at least one of the following conditions occurs:

- Relevant modifications of the special process or of the process parameters
- Maintenance operations or equipment modifications that may affect the performances of the equipment
- Equipment change or relocation of one or more equipment (includes equipment move and facility change)
- Inactivity exceeding one year
- Other conditions called out in the applicable process specifications
- Change of Supplier Company name
- Revision of a process specification or issue of a new (superseding) specification, when applicable
- New RFVA

The requalification requires the re-issue of the DQP and *shall* be performed as the initial validation, unless differently specified by the applicable specifications.

In case of modifications that can clearly affect only specific parameters and not the process in the whole, the testing plan may be focused on those parameters but *shall* demonstrate that the changes do not affect process compliance.

The Supplier *shall* immediately inform the LH Laboratory and SQA if at least one of the conditions that require requalification occur, and submit all the requested documentation.

In case of facility change, the supplier *shall* notify LH prior to start with any relocation.

In case of revision of the process specifications called out in the scope of the DQP or in case of issue of a superseding (new) specification, an assessment[25] for impact on the process *shall* be performed by the Supplier and documented on file as record equivalent to a qualification report. This assessment and any process modification/update *shall* be implemented within six months since the issue date of the specification, unless differently specified in the Process Specification or otherwise authorized by LH Engineering.

Changes due to revised specifications that have no impact on the process or in the process control testing do not require the re-issue of the DQP, that will remain valid until the next expiry date.

In case of issue of a new (superseding) specification, the DQP *shall* be reissued.

5.6 Nadcap approval

LH mandates the Nadcap accreditation to suppliers performing special processes in the applicable Nadcap commodities listed in Appendix 2.

Lack of commitment of the supplier to achieve and maintain a Nadcap accreditation may result, upon LH discretion, to discontinue the approval/renewal of the special process or to apply additional surveillance/quality requirements. The costs of extra surveillance *will* be charged to the Supplier.

LH can perform Special Process audits at a non-Nadcap approved Supplier site using the applicable Nadcap checklists.

LH Suppliers Nadcap approved *shall*:

- Clearly indicate LH as Subscriber/Customer in eAuditNet for each Nadcap Audit to be performed;
- Include all the applicable LH supplemental Nadcap checklists in the audit scope and
- Regularly submit LH parts during jobs audits.
- When applicable, clearly indicate the LH process specifications used (for example during CP Nadcap Audit)

A current Nadcap accreditation maintained as described above may be a valid justification for reducing any LH qualification activities/verifications for DQP and special processs surveillance/DQP renewal. In this case, the following alleviations apply:

- The LH Laboratories issuing the DQP may skip the verification of the requirements already part of the Nadcap scope approval[35], limiting the checks to the specific LH requirements.
- LH may, missing any specific elements of risk or quality issues, waive special process oversight audits/visits for first approval and/or requalification. The DQP renewal may be granted based on an updated list of personnel and equipment.

- For Special Processes per National/International Specifications having these specifications in the audit Scope, a test report (see Appendix 1) can be waived and the DQP granted only based on a Nadcap accreditation current.

The Supplier *shall* immediately notify to LH SQA and The LH Quality Control / Laboratory in case a Nadcap certification is lost

5.7 Personnel Qualification for Special Processes

The supplier *shall* arrange and keep updated the list of personnel assigned with detail of relevant competence, tasks and any limitations. The personnel *shall* be designated on the basis of minimum performances to be satisfied related to:

- physical fitness for the task,
- documented evidence of the training results and of attended theoretical and practical courses and experience,
- detailed knowledge of the system/equipment and process (theoretical and practical),
- evidence of operational continuity and skill for the task.

All the applicable requirements related to the above *shall* be addressed in a documented supplier procedure, acceptable to LH.

This procedure *shall* flow-down all the applicable requirements (like contractual requirements, process specifications, Nadcap checklists).

This procedure *shall* also address in detail to the methods for: physical fitness verification; training; examination; issue of approval and maintenance for the specific skills; records.

The required training and coaching *shall* cover all the applicable process specifications, testing/inspection methods and equipment. The training programs *shall* be addressed to the continuous improvement of the personnel and *shall* also cover specifications and equipment updates.

The list of the personnel assigned to the special processes and evidence of approval *shall* be submitted to LH as part of the validation report for initial special process validation, revalidation and renewal.

The personnel *shall* be identified on the DQP or, as alternative, it is acceptable to identify the supplier report where is listed the personnel qualified for the Special Processes.

The supplier is responsible to keep this list updated, to be submitted to LH at any time upon request and during the visits at the supplier facility.

During the activity performed to approve the supplier Quality Management System and during any surveillance visit, SQA *shall* verify how the supplier qualifies his personnel involved in the Special Processes.

Remark: for all requirements to personnel assigned to NDT including qualification, training, maintenance, etc, AWPS009X applies.

5.8 Special Process Equipment management

The Supplier is responsible to assure that all the equipment is clearly and appropriately identified with id number of the equipment, description of the process and of every single operation performed in every single station.

Any inactivity of the equipment/process *shall* be immediately identified under responsibility of the processor/shop manager with devices (i.e. visible tables indicating maintenance etc.) that clearly prevent the personnel running the process.

The process control tests may not be performed during the process inactivity, but *shall* be performed before the re-start of the process, unless there are conditions for loss of qualification.

6 DQP Suspension/Cancellation/Lapse

Supplier DQPs may be suspended or cancelled upon discretion of LH in case of:

- Quality issues related to the approved Special Process
- Change of supplier facility without notification to LH
- Missing process re-validation when the conditions for re-validation occur
- Supplier delays on providing the validation reports that may cause in delay in the DQP renewal beyond the expiration date
- End/interruption of contract or supplier activities for LH
- Suspension of Supplier status of LH approved Supplier.
- Any other violations to this procedure

Cancellation, laps and/or suspension of a DQP will cause as consequence the quarantine of the parts and management by concessions.

7 Exceptions to LH Process Specifications (Request for Variation Approvals – RFVA)

Exceptions to applicable LH process specifications *shall* be managed through RFVA using the appropriate form (see QRS-01). The RFVA *shall* be submitted to LH Engineering through the competent LH Laboratory or Quality Control responsible for DQP approval.

The assessment of the RFVA (performed by LH Engineering) could result in approval (full approval or with limitations) or rejection.

Remark: an approved DQP is not a valid document to authorize deviations to Process Specifications without an approved RFVA.

8 Special Processes performed by *Manufacturer* Suppliers per International or Proprietary Specifications

Manufacturer Suppliers performing Special Processes according to International or Proprietary Specifications on LH articles *shall* have an effective system in place to qualify, control and maintain these special processes. The Supplier *shall* identify the Processes listed in Appendix 2 as Special Processes.

This system *shall* include documented procedures to manage:

- Identification of Special Processes and use for production
- Special Process Qualification
- Special Process Control and maintenance, to make sure the approval is mantained
- Training and Qualification of personnel involved with the process, qualification of equipment, methods and materials

For these Suppliers it is not required process approval by DQP granted by LH.

Remark: a current Nadcap accreditation can be considered a valid condition to cover the capabilities above.

The Supplier Capabilities to manage and control these special processes are assessed by SQA during the Supplier Quality approval and during surveillance.

The Supplier Control system mentioned above, with the applicable procedures and with a list Special Processes and Specifications used on LH articles *shall* be described in the Quality Plan for new development products (see QRS-108)

9 Records

Record	Retention period
DQP	3 years starting from the date of cancellation/ deletion / superseded / expiry
RFVA	Life Of Product + 3 years
Validation Test Reports	3 years starting from the date of cancellation/ deletion / superseded / expiry

10 Appendixes, Annexes and Forms:

- Appendix 1: Minimum Contents of Qualification/Renewal and Requalification Report
- Appendix 2: Table of Special Processes
- Appendix 3: Declaration for Qualification of the Process (DQP)

Appendix 1: Minimum content of the Qualification/Renewal/Requalification Report

List of the applicable specifications

List of the technological specifications applicable for the primary special process (i.e. heat treating) and of all the auxiliary specifications used in support of the primary process (i.e.: testing, calibration, pyrometry, cleaning/degreasing) and revision level.

List of the applicable procedures and instructions

List of the internal procedures and instructions governing the Special Process and the auxiliary processes (testing, calibration, cleaning, etc.), with revision level. Includes the qualification of personnel.

Short description of the process

Clearly describe the SP, any sub-processes and relevant information, such as limitations

List of equipment and description:

Fixed and portable equipment, including the following information:

- Identification Number
- Manufacturer
- Type model
- Serial Number
- Installation year
- Functional and geometrical properties
- Measuring/monitoring instruments used for the process and evidence of calibration current

Validation tests

Validation tests requested per applicable specifications to demonstrate compliance, inspections and calibrations, including test reports with evidence of requirements and achieved results.

Consumable materials

List of consumable materials used for the process

Plant layout

Map of the areas where the process is performed with equipment location

List of Qualified Personnel authorized to perform the process

Qualified operators, inspectors, testing personnel, relevant responsible people/supervisors

Exceptions from the applicable requirements

Any deviations *shall* be clearly declared, including copy of approval documents (i.e.: RFVA) signed by the competent authorities.

Checklists used/verification criteria

Copy of the checklist(s) used to demonstrate compliance to the applicable requirements/specifications, filled in with the results of the internal assessment, or other verification criteria used to demonstrate compliance.

Nadcap approval

Specify if the process is Nadcap approved or not. If the process is Nadcap approved, the supplier *shall* provide copy of the Scope of Approval.

Appendix 2: Table of LH Special Processes

Manufacturing Special Processes	**Nadcap Commodity**
Heat Treating and thermochemical treatments, stress relieving	HT
Chemical and galvanic treatments for protection and for surface preparation, including brush/touch-up applications. De-embrittlement processes, when applicable, shall be included in the DQP of the main process.	CP
Vacuum metal (cadmium) deposition	CP
Application of solid (dry) film lubricant	CP
Chemical milling	CP
Painting of helicopter/aircraft blades	CP
Structural bonding, curing and composite manufacturing	COMP
Welding, including ALM process (Additive Layer Manufacturing)	WLD
Shotpeening	SE
Thermal spray coating	CT
Physical Vapour Deposition (PVD)	CT
Material surface preparation for bonding	CP/COMP
Brazing	HT/WLD
Electrical Discharge Machining (EDM)	NM
Chemically assisted isotropic super-finishing of metallic materials	Not identified by Nadcap
External thread rolling	Not identified by Nadcap
Thermal coupling/assembly of parts	Not identified by Nadcap
Swaging of flight control rods and connecting rods	Not identified by Nadcap
Impregnation of castings	Not identified by Nadcap
Hot Isostatic Pressing of castings (HIP) – *Hipping* of castings	HT
Application of permanent resin cover	Not identified by Nadcap
Crimping and assembly of electrical cables	Not identified by Nadcap
Inspection (NDT) Special Processes	**Nadcap Commodity**
Radiographic and Radioscopic Testing (RT)	NDT
Etch Inspection (EI)	NDT/CP
Liquid Penetrant Testing (PT)	NDT
Magnetic Testing (MT)	NDT
Eddy Current Testing (ET)	NDT
Ultrasonic Testing (UT)	NDT
Bond Test (BT). *For this process only personnel qualification is required*	Not identified by Nadcap

Acronyms:

HT: Heat Treating
CP: Chemical Processing
COMP: Composites
NDT: Non Destructive Testing
WLD: Welding
SE: Surface Enhancement
CT: Coatings
NM: Non-conventional Machining

Additional remarks:

Within the production documents (cycles or other shop documents), the cycle operations
describing or specifying Special Processes *shall* be clearly pointed out (for instance with
the letter “S” or underlined or other similar).

Auxiliary processes

Some of the auxiliary processes may be also Special Processes. The focus is on the fact that they cannot be approved with a specific approval (DQP) outside of the primary Special Process). The auxiliary processes cannot be approved by a specific dedicated DQP because they require awareness of the requirements of the main process (e.g. maximum delay time of de-embrittlement after plating).

The following are considered auxiliary processes and cannot be approved by dedicated DQP but *shall* be assessed and included in the scope approval of the DQP of the main process:

- Cleaning or degreasing as surface preparation for a main process (heat treat, plating, etc.)
- Thermal treatment for hydrogen de-embrittlement after embrittling processes like plating/etching.
- Laboratory testing and inspections (hardness, conductivity, tensile, pyrometry, thickness, process controls, inspection of thread rolling etc.)

The auxiliary processes can only be used for captive applications (in support of the process performed by the processor) and *shall* be reviewed for approval with the main process with the same level of detail as the primary process, since they are as important as the primary.

The auxiliary specifications *shall* be listed in the DQP scope of approval of the main process.

Suppliers seeking for approval as independent test facilities need SQA approval as testing laboratories (the DQP is not applicable for testing laboratories).

Material Testing are identified by the following Nadcap Commodities:

- MTL: Metallic Material Testing
- NMMT: Non Metallic Material Testing

Appendix 3: Declaration for Qualification of the Process (DQP)

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Declaration of Qualification of the Process

Dichiarazione Qualifica Processo

N° xxxx/yyyy/zz

☐ INITIAL QUALIFICATION / *Qualificazione Iniziale* ☐ RENEWAL OF QUALIFICATION / *Rinnovo della Qualifica* ☐ REQUALIFICATION / *Riqualificazione* ☐ External / *Esterna* ☐ Internal / *Interna*

APPROVED SUPPLIER OR LH PLANT / *Fornitore o Sito LH*	RESPONSIBLE LH SITE / *Sito LH Responsabile*
PRODUCTION SITE / *Sito Produttivo*	DEPARTMENT - BUILDING / *Reparto - Edificio*

SPECIAL PROCESS / *Processo Speciale*

PROCESS DETAIL / *Dettaglio Processo*

APPLICABLE SPECIFICATIONS AND REVISION NUMBER (continue to page 2)
Specifiche Applicabili e Relativo Stato di Revisione (segue a pagina 2)

EQUIPMENT AND RELEVANT DATA / *Impianti e Dati Rilevanti*

APPROVED ACTIVITIES / *Attività Approvate*

LIMITATIONS / *Limitazioni*

THE PROCESS IS APPLICABLE FOR THE PRODUCTION OF PARTS P/N
Il processo è Applicabile alla produzione di Parti P/N

☐ AgustaWestland ☐ Bell ☐ Boeing ☐ Sikorsky ☐ AW609 ☐ ICH-47F ☐

PERONNEL ASSIGNED TO THE PROCESS / *Personale Addetto al Processo*

PRODUCTION RESPONSIBLE / *Responsabile Produzione*	QUALITY RESPONSIBLE / *Responsabile Qualità*
ASSIGNED PERSONNEL / *Personale addetto*	INSPECTORS / *Controllori*

RESPONSIBILITY: THE APPROVED LH FACILITY / SUPPLIER IS RESPONSIBLE TO PERFORM ALL TESTS REQUIRED BY APPLICABLE PROCESS SPECIFICATIONS
Responsabilità: il Reparto LH / Fornitore approvato è responsabile di eseguire tutte le prove richieste dalle Specifiche Applicabili
TRACEABILITY: RECORDS OF ALL PROCESS CONTROL TESTING PERFORMED AND RELATED RESULTS MUST BE AVAILABLE
Rintracciabilità: deve essere disponibile la registrazione di tutte le prove di controllo processo e relativi risultati

APPROVED DEVIATIONS-RFVAs / *Deviazioni-RFVA Approvate*

QUALIFICATION REPORT No. / *Rapporto di Qualifica N°*	QUALIFICATION REPORT DATE / *Data Rapporto di Qualifica*

DQP INITIAL VALIDITY DATE *Data inizio validità DQP*	DQP VALIDITY YEARS *Validità in anni DQP*	DQP EXPIRATION DATE *Data Scadenza DQP*

THIS DOCUMENT MUST BE DISPLAYED ON THE EQUIPMENT OR AS CLOSE AS POSSIBLE
Il presente documento deve essere esposto sugli Impianti o nelle immediate vicinanze

PREPARED BY *Preparato Da*	DATE *Data*	LABORATORY RESPONSIBLE *Responsabile di Laboratorio*	DATE *Data*	QUALITY CONTROL MANAGER *Responsabile Quality Control*	DATE *Data*

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Declaration of Qualification of the Process

Dichiarazione Qualifica Processo

N° xxxx/yyyy/zz

PROCESS CONTROL TESTS AND INSPECTIONS TO BE PERFORMED *Prove di Controllo Processo e Ispezioni da Eseguire*	FREQUENCY *Frequenza*	*REFERENCE DOCUMENTS* *Documenti di Riferimento*

REVISIONS / *Revisioni*

REMARKS / *Note*

COMMODITY / *Commodity*

Continued from page 1 / *Segue da pagina 1*

APPLICABLE SPECIFICATIONS AND REVISION NUMBER / *Specifiche Applicabili e Relativo Stato di Revisione*

ASSIGNED PERSONNEL / *Personale Addetto*	INSPECTORS / *Controllori*